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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,946	08/22/2001	Charles Chauveau	C1190/20008	5350

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CAESAR, RIVISE, BERNSTEIN,
COHEN & POKOTILOW, LTD.
11TH FLOOR, SEVEN PENN CENTER
1635 MARKET STREET
PHILADELPHIA, PA 19103-2212

EXAMINER	
GOLLAMUDI, SHARMILA S	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 12/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/830,946	CHAUVEAU ET AL.	
	Examiner	Art Unit	
	Sharmila S. Gollamudi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 September 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *48-53 and 56-74* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *48-53 and 56-74* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt of Amendments/Remarks filed on September 24, 2004 is acknowledged. Claims **48-53 and 56-74** are pending in this application.

Claim Rejections - 35 USC § 112

The rejection of claims 48-74 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn in view of amendment 7/21/03 deleting the new matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 69 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 69 recites "wherein the permeabilizing agent is selected from the group consisting of silicas with a high affinity for aqueous solvents, maltodextrins, beta-cyclodextrins and mixtures thereof." However, parent claim 61 already recites this limitation. Therefore, the intended limitation of this claim is unclear.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 48-53 and 56-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ohno et al (5,958,453) in view of Gowan (5,876,759).

Ohno et al teach a solid pharmaceutical composition with improved disintegrability. The composition contains 50g meclizine hydrochloride , 0.25g scopolamine, 40g caffeine, 20g vitamin B, 264.8 erythritol, 264.95g mannitol, 120g crystalline cellulose, 40g crospovidone, and 1% magnesium stearate. Example 6 teaches the use of 1% light anhydrous silicic acid and magnesium stearate. The composition dissolves in the oral cavity in less than 40 seconds. See examples. The mannitol utilized has a particle size of 150 mesh and erythritol has a particle size of 50 mesh. See column 5, lines 40-50 and column 4,lines 48-55. Ohno teaches the use of conventional additives used in the art such as sweeteners (aspartame, stevia, etc.), colorants, lubricants, binders, etc. See column 6, lines 5-15.

Ohno et al do not teach a coated active.

Gowan discloses a rapidly disintegrating tablet (30 seconds or less) containing coated acetaminophen (23%), mannitol (57%), microcrystalline cellulose (15%), aspartame, colloidal silicon dioxide (.06%), and stearic acid (.75%). Gowan teaches the particle size of the coated

active and other components are generally less than 400 microns. Note examples. Gowan teaches the use of a coating for the pharmaceutical active to provide taste-masking properties. See column 4, lines 35-50.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings Ohno et al and Gowan and utilize a coated active in the composition. One would have been motivated to do so since Gowan teaches coating an active with a polymer to provide for taste-masking properties. Further, one could reasonably succeed by combining the references and since both references are directed to rapidly disintegrating dosage forms that dissolve in the oral cavity in less than 40 seconds.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 48, 50-54, 61, 63,65, and 67-68 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 and 11-12 of U.S. Patent No. 6,106,861 in view of Ku et al (5,994,348). Although the conflicting claims are not identical, they are not patentably distinct from each other because the

claimed subject matter in instant application and US patent '861 are obvious modifications of each other.

Instant application recites a multiparticulate tablet, which disintegrates in contact with the saliva in the mouth in less than 40 seconds, wherein it is based on:

A) particles of coated active principle, and

B) mixture of excipients being free of effervescent agents and the ratio of excipient mixture to coated active principle particles being 0.4 to 6 parts by weight, the mixture of excipients comprising: a disintegration agent; a soluble diluent with binding properties which is a polyol with less than 13 carbon atoms, with an average particle diameter of 100 to 500 um, a lubricant, a permeablizing agent, the proportion of disintegration agent being 1 to 15% by weight and the proportion of soluble agent being 30 to 90% by weight, based in each case on the weight of the tablet. Amended claims recite the inclusion of a permeabilizing agent selected from silicas, maltodextrins, and beta-cyclodextrins.

Dependent claims recite the Markush group xylitol, sorbitol, and maltitol as the soluble diluent. Dependent claims recite aspirin, ibuprofen, and paracetamol.

US patent claims a multiparticulate tablet, which disintegrates in the mouth in less than 40 seconds, wherein it is based on:

A) particles of coated active principle and

B) mixture of excipients of 3-15% of a disintegrant selected from crosslinked PVP or crosslinked sodium carboxymethylcellulose, and 40-90% soluble diluent

with binding properties which is a polyol with less than 13 carbon atoms selected from mannitol xylitol, sorbitol, and maltitol. Dependent claims recite aspirin, ibuprofen, ketoprofen, loperamide, and paracetamol.

US patent does not claim a permeabilizing agent.

Ku et al teach a pharmaceutical composition with excellent wetting, disintegration, and rapid release properties (col. 2, lines 5-15). Ku teaches the use of one or more disintegrants, which are capable of facilitating the break up of a tablet when placed in contact with an aqueous medium. Among the disintegrants that meet this criteria, croscarmellose is taught in a range of 2-5%. See column 3, line 65 to column 4, lines 20. Ku teaches the use of anti-adherents such as .25-5% silicon dioxide reduce the stickiness of the formulation and prevent adherence to metal surfaces. (col. 4, lines 20-30). Further, Ku teaches the combination of magnesium stearate and silicon dioxide provides a superior lubrication effect while minimizing any decline in tablet dissolution performance (col. 5, lines 59-65).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize a silica in the pharmaceutical composition. One would have been motivated to do so since Ku teaches the advantages of using an anti-adherent agent in reducing the stickiness of the composition to metal surfaces during the process of making the dosage forms.

Therefore, the inclusion of permeabilizing agents in the instant application is deemed to be an obvious modification to the subject matter of US patent.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharmila S. Gollamudi
Examiner
Art Unit 1616

SSG

GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600